CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INITIAL STATEMENT OF REASONS FOR THE PROPOSED AMENDMENTS OF THE CIRM MEDICAL AND ETHICAL STANDARDS SECTIONS 100010-100050, AND SECTION 100070

HEARING DATE: None scheduled.

CLOSE OF PUBLIC COMMENT: August 22, 2016

SUBJECT MATTER OF PROPOSED AMENDMENTS: Medical and Ethical Standards

SECTIONS AFFECTED: The proposed amendments apply to Chapter 2 and sections 100010-100050, and section 100070 of Title 17 of the California Code of Regulations.

The following discussion of "Purpose" and "Rationale" pertain to each section and the proposed amendment as indicated below.

SECTION 100010 – SCOPE OF CHAPTER 2 – STEM CELL RESEARCH:

Purpose:
The amendments conform the section to the use of the term "Awardees" instead of "all institutions," consistent with the use of that term in the definitions section of section 100020. The amendments also delete obsolete references to specific subdivisions of section 100020.

Rationale:
The amendments conform to the agency's use of the term "Awardee" in its grant administration policies for consistency. The deletion of obsolete references to subdivisions of section 100020 are intended to eliminate confusion.

SECTION 100020 – DEFINITIONS

Purpose: The amendments define the following terms:

(b) "Awardee" means an organization that is the recipient of an award from CIRM and that is legally responsible and accountable for their use of the funds provided and for the performance of the CIRM-funded project or activity. The Awardee is the entire legal entity even if a particular component is designated in the notice of award. Campuses of the University of California shall be considered as separate and individual Awardees.

(g) "Human Subjects Research" is research defined by Title 45, Code of Federal Regulations, Part 46 (Protection of Human Subjects), revised June 23, 2005.

Rationale: These definitions conform to the terms already in use by CIRM in its grants administration policies applicable to CIRM-funded research and ensure consistency with the terms as used by the federal government. This will ease compliance and eliminate confusion for institutions that accept federal grants for research. The definition of "Human Subjects Research" is relocated to this section from section 100070, subdivision (c). This change ensures definitions can be found in the appropriate "definitions" section of the chapter.

SECTION 100030 – ACTIVITIES NOT ELIGIBLE FOR CIRM FUNDING

Purpose: The amendments clarify that that among the activities ineligible for CIRM funding are activities relating to the breeding any animal into which covered stem cells from a covered stem cell line have been introduced such that they could contribute to the germ line.

Rationale: The amendments clarify the scope of this prohibition to ensure that the prohibited activity only reaches the introduction of stem cells that could contribute to the germ line and thus have an impact on the species. This policy is consistent with the 2010 National Academies' Guidelines for Human Embryonic Stem Cell Research and is designed to allow multigenerational Safety studies of stem cell therapies in animal models.

SECTION 100040 – INSTITUTIONAL ASSURANCE OF COMPLIANCE

Purpose: The amendments make non-substantive changes to conform to the chapter's use of the term "awardee" in place of "institution." The amendments also clarify the scope of the SCRO and IRB requirement to state that Awardees conducting human subjects research or research requiring SCRO committee review and approval under Title 17, California Code of Regulations section 100070, shall:

(1) Designate one or more SCRO committee(s) established in accordance with the requirements of Code of California Regulations, title 17, section 100060; and
(2) Designate one or more IRB(s).

Awardees shall ensure that that clinical personnel conducting human subjects research who have a conscientious objection not be required to participate in providing donor information or securing donor consent for research use of gametes or embryos. That privilege shall not extend to the care of a donor or recipient.

Rationale: The amendments are necessary to provided clarity as to the assurance provided by Awardees that they will establish necessary SCRO and IRB panels in the event the research contemplates human subjects research. The amendments to subdivision (c) are non-substantive and simply emphasize that the provision applies to research conducted on human subjects.

SECTION 100050 – COMPLIANCE

Purpose: The amendments make non-substantive changes to eliminate material duplicative in the governing grants administration policy for the specific award. Grantees must report promptly to CIRM any failure to comply with the terms and conditions of an award. Failure to comply with the provisions of this chapter, as well as any other conditions of the award, are set forth in the Grants Administration Policy that govern the award.

Rationale: The amendments are necessary to avoid confusion. The deleted language is already addressed in the grants administration policy that governs CIRM awards and which address the consequences for failure of compliance for all applicable CIRM policies and regulations.

SECTION 100070 – SCRO COMMITTEE REVIEW AND NOTIFICATION

Purpose: The amendments make technical non-substantive amendments to eliminate extraneous language. In addition, the amendments in subdivision (c) relocate the definition of Human Subjects Research to section 100020 – Definitions.

The amendments to subdivision (e) state that the introduction of covered stem cells into hon-human mammalian blastocysts or fetuses or introducing human neural progenitor cells into the brain of non-human animals at any state of embryonic, fetal or postnatal development may not commence without SCRO committee review and approval in writing. Studies involving postnatal animals performed pursuant to a FDA Investigational New Drug (IND) or Device application are exempt from SCRO committee review and approval.

Rationale: The amendments restate the circumstances requiring SCRO approval but provide an exemption in the circumstance identified. In these such studies where the FDA has already reviewed and approved the research protocol, CIRM will eliminate the duplicative SCRO review requirement. In addition, animal studies are already overseen by an IACUC review.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS:

A. Documents or Laws:

None.

B. Public Input:

Meetings of the Standards Working Group on April 2-3, 2015 and February 4, 2016; and of the ICOC on July 23, 2015.

Copies of the documents referenced above are available at the offices of CIRM located at 1999 Harrison Street, Oakland California, 94612. Alternatively, transcripts and agendas for public meetings are available on CIRM's website, www.cirm.ca.gov.

MANDATE FOR SPECIFIC TECHONOLOGIES OR EQUIPMENT:

The proposed amendments do not mandate the use of specific technologies or equipment.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES:

In view of information currently possessed, no reasonable alternative considered would be more effective in carrying out the purposes for which the amendments are proposed, or would be as effective as the amendments proposed.

CIRM invites interested persons to present statements or arguments with respect to alternatives to the proposed amendments at the scheduled hearing or during the written comment period.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THAT WOULD LESSON ANY ADVERSE IMPACT ON SMALL BUSINESS:

CIRM has made the initial determination that the proposed amendments will not have an adverse impact on small business. This regulation large academic and well-capitalized biotechnology institutions. As such, no private conduct or commercial activity by a business of any size is being regulated. Moreover, the amendments provide a voluntary option for Loan Recipients, and thus requires no action on the part of CIRM Loan Recipients.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS:

CIRM has made the initial determination that the proposed amendments will not have a statewide adverse economic impact. This action is not expected to have a direct impact on the creation or elimination of jobs, nor the creation of new businesses or elimination of existing businesses, nor the expansion of business currently doing business within the State of California because the amendments affect only internal operations. The use of grant funds is required neither by law nor these regulations. To the extent the regulations facilitate use of the funds and encourage development of intellectual property and return to the state as required by law, and to the extent California institutions apply for and receive research funds, such requirements are indirectly attributable to increased economic activity spurred by the investment research funds in the state and resultant positive business and employment development. Also, to the extent the amendments makes it possible for the expenditure of research funds in the state, and to the extent that research results in medical treatments and cures for chronic disease and injury, the amendments indirectly benefit the health and welfare of California residents who will benefit from such treatments and cures.

ECONOMIC IMPACT ANALYSIS REQUIRED BY GOVERNMEND CODE SECTION 11346.3, SUBDIVISION (b)

Action: The regulatory action amends the existing loan administration policy regulation (and the policy incorporated thereby) (section 100800). The amendments provide a CIRM research loan recipient with the option to extinguish it's obligations under the Loan Policy, and instead treat the loan as a Grant under the conditions identified. The action does not regulate a commercial or

private activity of any individual or institution but provides flexibility to CIRM loan recipients with flexibility in how it chooses to book its loan obligations.

Impact:

Under section 3 of the "California Stem Cell Research and Cures Act," which established the California Institute for Regenerative Medicine, funds for this agency are continuously appropriated without regard to fiscal year and not subject to budgetary control. The Act requires CIRM adopt rules to apply to Grants and Loans made by the agency.

CIRM has determined that that proposed regulatory action has no direct impact on small businesses. Virtually all applicants for CIRM funding are either large academic nonprofit institutions or well-capitalized biotechnology ventures. As such, the regulation is not expected to adversely impact small business as defined in Government Code section 11343.610. Application for grant funds is voluntary and grant awards are required by Proposition 71 to include a prescribed additional amount to cover any costs associated with administration of the grant by grant recipients.

This action is not expected to have a direct impact on the creation or elimination of jobs, nor the creation of new businesses or elimination of existing businesses, nor the expansion of business currently doing business within the State of California because the regulation affect only administrative requirements regarding use of loan and grant funds. The use of loan funds is required neither by law nor these regulations. To the extent the regulation facilitates use of the funds and encourage development of intellectual property and return to the state as required by law, and to the extent California institutions apply for and receive research funds, such requirements are indirectly attributable to increased economic activity spurred by the investment research funds in the state and resultant positive business and employment development. Also, to the extent the regulation makes it possible for the expenditure of research funds in the state, and to the extent that research results in medical treatments and cures for chronic disease and injury, the regulation indirectly benefit the health and welfare of California residents who will benefit from such treatments and cures. Finally, to the extent that a loan recipient with a forgiven loan is able to convert that potential liability to a grant and remove the debt from its accounting, that will help loan recipients improve their financial standing.